

LICENSURE REGULATIONS
HEMATOPOIETIC PROGENITOR/STEM CELL TRANSPLANTATION
PROGRAM

105 CMR 130.000 is amended by adding the following new sections:

130.510: Purpose

105 CMR 130.510 through 130.580 set forth the licensure standards for a hospital-based Hematopoietic Progenitor/Stem Cell Transplantation Program. Any hospital wishing to provide hematopoietic progenitor/stem cell transplantation shall request prior approval from the Department.

130.520: Definitions

The following definitions apply in 105 CMR 130.000 when used in regard to hematopoietic progenitor/stem cell transplantation services and programs.

Cell Processing Facility means a clinical laboratory that processes and stores hematopoietic progenitor/stem cell components for clinical transplantation programs.

Collection means any procedure for harvesting hematopoietic progenitor/stem cells regardless of technique or source.

Collection Facility or Service means a facility or service that collects or harvests hematopoietic progenitor/stem cells for clinical transplantation programs.

FAHCT Standards means the current North American edition of *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation* published by FAHCT.

Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT) is the national accrediting body for hematopoietic progenitor/stem cell collection, processing & transplantation services.

Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services (HPCCPTS) means a service performing blood and marrow transplantation in the treatment of human disease. The service includes all phases of the collection, processing and administration of hematopoietic progenitor/stem cells. This includes but is not limited to cells isolated from bone marrow, peripheral blood, or placental/umbilical cord blood, and any of a variety of manipulations including removal

or enrichment of various cell populations, expansion of hematopoietic cell populations, cryopreservation, infusion, expansion or activation of mononuclear cell populations for immunological therapy, and genetic modification of lymphoid or hematopoietic cells, when the cells are intended to permanently or transiently engraft in the recipient, and/or be used in the treatment of disease. HPCCPTS does not include the collection, processing or administration of erythrocytes, mature granulocytes, platelets, plasma or plasma-derived components intended for transfusion support.

Hematopoietic Progenitor/Stem Cell Transplantation Program or Clinical Transplantation Program consists of an integrated medical team housed in geographically contiguous or proximate space with a single Program Director, common staff, training programs, protocols and quality assessment systems licensed pursuant to 105 CMR 130.510 through 130.580.

Hematopoietic Progenitor/Stem Cells means primitive pluripotent hematopoietic cells capable of self-renewal as well as maturation into any of the hematopoietic lineages, including committed and lineage-restricted progenitor cells, unless otherwise specified in the FAHCT Standards, regardless of tissue source.

Labeling means steps taken to identify the original hematopoietic progenitor/stem cell collection, any components, and any component modifications; to complete the required reviews; and to attach the appropriate labels.

Manipulation means an ex vivo procedure(s) that selectively removes, enriches, expands or functionally alters hematopoietic progenitor/stem cells

Processing means all aspects of manipulation, labeling, and infusion of harvested material, regardless of source.

Transplantation means the infusion of autologous, syngeneic or allogeneic hematopoietic progenitor/stem cells with the intent of providing transient or permanent engraftment in support of therapy of disease.

130.525: Department Approval to Provide Hematopoietic Progenitor/Stem Cell Transplantation Program

A hospital licensed or operated by the Commonwealth pursuant to M.G.L. c. 111, s. 51, that provides or intends to provide an hematopoietic progenitor/stem cell transplantation program shall apply for and receive approval from the Department in order to provide the service. The Department shall grant its approval if the hospital meets the requirements in 105 CMR 130.510 through 130.580, complies with the standards of the Foundation for the Accreditation of Hematopoietic Cell Therapy

(FAHCT) and receives and maintains accreditation by FAHCT for the clinical transplantation program.

130.527: Program Requirements

(A) The Program shall be part of a comprehensive hematopoietic progenitor/stem cell collection, processing and transplantation service.

(B) A clinical program that includes non-contiguous institutions in the same metropolitan area shall have a single Program Director, common protocols, staff training, quality assessment systems, review of clinical results and evidence of frequent, regular interaction by all members of the multidisciplinary team.

(C) A hospital licensed to provide an hematopoietic progenitor/stem cell transplantation program shall provide or arrange for collection and processing of hematopoietic progenitor/stem cells through collection facilities or services and cell processing laboratories that meet FAHCT accreditation standards. Collection facilities and/or processing laboratories serving one or more clinical transplantation programs are acceptable.

(1) If the collection facility or service used by the hospital transplantation program is located outside the United States, the collection facility must be affiliated with the National Marrow Donor Program (NMDP) or the World Marrow Donor Association (WMDA).

(2) The cell processing facility shall be:

- (a) for facilities located within Massachusetts, a licensed, federally certified clinical laboratory, as defined under 42 USC 263A (the Clinical Laboratory Improvement Amendments), or
- (b) for laboratories located outside Massachusetts but within the United States, a federally certified clinical laboratory, as defined under 42 USC 263A (the Clinical Laboratory Improvement Amendments), or
- (c) for laboratories located outside of the United States, a laboratory that is affiliated with the National Marrow Donor Program (NMDP) or the World Marrow Donor Association (WMDA).

(D) Autologous hematopoietic progenitor/stem cell transplantation may be performed in a separately licensed freestanding clinic if:

- (1) the clinic transplantation services are a formal part of a hospital-based transplantation program and
- (2) the hospital-based transplantation program has a current, written collaboration agreement with the freestanding separately licensed clinic that describes the

services and responsibilities of each entity and complies with the requirements of 105 CMR 130.536.

130.530: Incorporation of *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation*

In addition to the requirements in 105 CMR 130.510 through 580, each hospital that provides or intends to provide hematopoietic progenitor/stem cell transplantation shall at a minimum meet the requirements of the current North American edition of *Standards for Hematopoietic Progenitor Cell Collection, Processing & Transplantation* published by the Foundation for the Accreditation of Hematopoietic Cell Therapy (FAHCT).

130.535: Prerequisites for Pediatric Transplantation Program

A hospital that provides or intends to provide a hematopoietic progenitor/stem cell transplantation program for pediatric patients shall have a licensed Level III pediatric service.

130.536: Prerequisites for Autologous Hematopoietic Progenitor/Stem Cell Transplantation Services Provided in a Freestanding Clinic

If, as part of a hospital-based hematopoietic progenitor/stem cell transplantation program, the hospital intends to provide autologous hematopoietic progenitor/stem cell transplantation services in a separately licensed freestanding clinic, the hospital must have a written, current collaboration agreement with that clinic that describes the responsibilities of each entity. The collaboration agreement shall at a minimum:

- (1) Describe the services to be provided at the clinic site;
- (2) Describe the support services available at the hospital site, with particular attention to availability for patient care consultation by all members of the multidisciplinary team, including but not limited to physicians, nurses, nutritionists, social workers, physical therapists and psychologists;
- (3) Describe the oversight responsibilities of the hospital;
- (4) Identify a physician or nurse coordinator on site at the clinic;
- (5) Describe the quality assessment and assurance programs for transplantation at the clinic site, with particular attention to how the assessment data is used to improve services and how the data is integrated in the both the clinic's and the hospital's quality assurance programs; and
- (6) Be signed and dated by the Hospital Administrator, Hospital Vice President of Nursing or Clinical Services, Hospital Hematopoietic Progenitor/Stem Cell Transplantation Program Director, Clinic Medical Director and Clinic Physician or Nurse Coordinator.

130.540: Application to Provide Hematopoietic Progenitor/Stem Cell Transplantation Program

(A) A hospital licensed or operated by the Commonwealth pursuant to M.G.L. c. 111, s. 51, that provides or is seeking to provide an hematopoietic progenitor/stem cell transplantation program shall provide documentation to the Department that it has received and maintains accreditation by FAHCT. A copy of FAHCT accreditation documentation shall be submitted to the Department upon receipt from FAHCT.

(1) By no later than July 12, 1998, a hospital providing autologous and allogeneic hematopoietic progenitor/stem cell transplantation services on or before June 12, 1998 shall submit to the Department a statement, signed under pains and penalties of perjury by a person authorized to act on behalf of the applicant, that attests that the applicant's transplantation program meets the FAHCT accreditation standards for autologous and allogeneic transplantation services and that by no later than September 12, 1998, the hospital will apply for accreditation by FAHCT and provide the Department with written confirmation of the filing.

(2) By no later than July 12, 1998, a hospital providing only autologous hematopoietic progenitor/stem cell transplantation services on or before June 12, 1998 that intends to expand the transplantation program to also provide allogeneic transplantation services, shall submit to the Department a statement signed under pains and penalties of perjury by a person authorized to act on behalf of the applicant, that attests that the applicant's transplantation program meets the FAHCT accreditation standards for autologous transplantation services and that the transplantation program will apply for accreditation by FAHCT for autologous transplantation no later than September 12, 1998 and provide the Department with written confirmation of the filing. The hospital shall file a separate notice regarding allogeneic transplantation as required by 105 CMR 130.540 (A)(4).

(3) Subsequent to receipt of the documentation required by 105 CMR 130.540(A)(1) or (2), the Department shall grant a provisional license for the program that identifies the type of transplants performed (allogeneic and/or autologous).

(a) If satisfactory written documentation of accreditation by FAHCT by type of transplant performed is not received by the Department within two years from the application date for accreditation, the Department shall notify the applicant that the Department has not received documentation of accreditation by

FAHCT and offer the applicant the opportunity to submit the documentation within two weeks or such other time period as the Department shall define.

(b) If the applicant does not submit the documentation required by 105 CMR 130.540(A)(3)(a), the Department shall revoke the provisional license and, without further hearing, refuse to issue a license for the transplantation program.

(4) Hospitals seeking to initiate an hematopoietic progenitor/stem cell transplantation program and hospitals providing autologous hematopoietic progenitor/stem cell transplantation services on or before June 12, 1998 that intend to expand the transplantation program to also provide allogeneic transplantation services shall submit to the Department at least 90 days prior to performing the first transplant, a written statement signed under pains and penalties of perjury by a person authorized to act on behalf of the applicant that attests that the applicant's transplantation service meets the FAHCT accreditation standards, except for the transplant volume requirement, that the hospital will file an application for accreditation by FAHCT once the program has completed, within a twelve month period, 10 of each type of transplant (allogeneic or autologous) for which it seeks accreditation, and the hospital will provide written confirmation of the filing of the accreditation application.

(5) Subsequent to receipt of the information required by 105 CMR 130.540(A)(4), the Department shall grant a provisional license for the service that identifies the type of transplant to be performed.

(a) Within 30 months from the date of the issuance of the provisional license, the hospital shall file the FAHCT accreditation application(s) and provide the Department with written confirmation of the filing.

(b) If the hospital fails to file the FAHCT application within the specified time period, the Department shall notify the applicant that the Department has not received satisfactory written documentation of filing for accreditation by FAHCT and offer the applicant the opportunity to submit the documentation within two weeks or such other time period as the Department shall define.

(c) If the applicant fails to submit the documentation required by 105 CMR 130.540(A)(5)(a) or (b), the Department shall revoke the provisional license and, without further hearing, refuse to issue a license for the transplantation program.

(d) If satisfactory written documentation of accreditation by FAHCT by type of transplant performed is not received by the Department within one year from

the application date for accreditation, the Department shall notify the applicant that the Department has not received documentation of accreditation by FAHCT and offer the applicant the opportunity to submit the documentation within two weeks or such other time period as the Department shall define.

(e) If the applicant does not submit the documentation required by 105 CMR 130.540(A)(5)(d), the Department shall revoke the provisional license and, without further hearing, refuse to issue a license for the transplantation program.

(B) In its letter of application, a hospital shall describe its hematopoietic progenitor/stem cell transplantation program. At a minimum, the description shall:

- (1) identify the Transplantation Program Director and provide a current curriculum vitae;
- (2) describe the type(s) of hematopoietic progenitor/stem cell transplantation the service will perform (autologous, allogeneic and/or syngeneic);
- (3) state whether this program will provide transplantation services to adults or pediatric patients, and if providing transplantation services to pediatric patients, indicate that the facility operates a licensed Level III pediatric service;
- (4) include projected transplantation volume by type [adult, pediatric, autologous, allogeneic (matched and mismatched), and syngeneic] for the first three years of licensure and an explanation of the basis for the projected volume;
- (5) identify any portion of the transplantation service which will be performed in a setting that is other than part of the licensed applicant facility, i.e., a separately licensed freestanding clinic, and include a copy of a signed, current collaboration agreement with that clinic;
- (6) indicate how many beds will be designated for use in the transplantation program and where the beds are located (building, floor, and department);
- (7) list any special equipment needed to perform transplantation; and
- (8) identify the cell collection and processing facilities or services the transplant program will regularly use. The applicant must indicate all cell collection and processing facilities or services used will meet FAHCT accreditation standards.

130.550: Issuance of an Amended Hospital License

Upon receipt of satisfactory written documentation of FAHCT accreditation by the type of transplants performed, the Department shall issue an amended hospital license which indicates that the hospital is authorized to perform hematopoietic progenitor/stem cell transplantation (allogeneic and/or autologous for adult and/or pediatric patients). For multiple hospitals that form one program, each hospital shall have the service added to its license. In such cases, the license will indicate that the hospital is part of a multiple hospital program.

130.560: Renewal of Hematopoietic Progenitor/Stem Cell Transplantation Program Licensure

The hospital shall apply for renewal of its license to perform hematopoietic progenitor/stem cell transplantation at the time of renewal of the hospital's license.

130.570: Reporting to the Department of Public Health

As a condition of maintenance and renewal of licensure of the program, the hospital shall submit information as requested by the Department regarding the transplantation service.

130.580: Denial, Revocation or Refusal to Renew Licensure of the Transplantation Program Based on Lack of Accreditation by FAHCT

Loss or denial of accreditation shall be reported in writing to the Department within 48 hours of receipt of such notice to the hospital from FAHCT. Failure to receive or maintain accreditation by FAHCT shall result in the denial, revocation or refusal to renew the licensure of the transplantation program without further hearing.

Under 105 CMR 130.020 Definitions, Service insert new sections (V) and (W)

(V) Hematopoietic Progenitor/Stem Cell Collection, Processing and Transplantation Services (HPCCPTS) means a service performing blood and marrow transplantation in the treatment of human disease. The service includes all phases of the collection, processing and administration of hematopoietic progenitor/stem cells. This includes but is not limited to cells isolated from bone marrow, peripheral blood, or placental/umbilical cord blood, and any of a variety of manipulations including removal or enrichment of various cell populations, expansion of hematopoietic cell populations, cryopreservation, infusion, expansion or activation of mononuclear cell populations for immunological therapy, and genetic modification of lymphoid or hematopoietic cells, when the cells are intended to permanently or transiently engraft in the recipient, and/or be used in the treatment of disease. HPCCPTS does not include the collection, processing or administration of erythrocytes, mature granulocytes, platelets, plasma or plasma-derived components intended for transfusion support.

(W) Hematopoietic Progenitor/Stem Cell Transplantation Program or Clinical Transplantation Program consists of an integrated medical team housed in geographically contiguous or proximate space with a single Program Director, common staff, training programs, protocols and quality assessment systems licensed pursuant to 105 CMR 130.510 through 130.580.

105 CMR 140.000 is amended by inserting the following new section immediately following 105 CMR 140.380:

105 CMR 140.381: Autologous Hematopoietic Progenitor/Stem Cell Transplantation

Autologous hematopoietic progenitor/stem cell transplantation may be performed in a separately licensed freestanding clinic if the clinic transplantation services are a formal part of a hospital-based hematopoietic progenitor/stem cell transplantation program. The clinic must have a written, current collaboration agreement with the hospital-based hematopoietic progenitor/stem cell transplantation program. The collaboration agreement shall, at a minimum:

- (1) Describe the services to be provided at the clinic site;
- (2) Describe the support services available at the hospital site, with particular attention to availability for patient care consultation by all members of the multidisciplinary team, including but not limited to physicians, nurses, nutritionists, social workers, physical therapists and psychologists;
- (3) Describe the oversight responsibilities of the hospital;
- (4) Identify a physician or nurse coordinator on site at the clinic;
- (5) Describe the quality assessment and assurance programs for transplantation at the clinic site, with particular attention to how the assessment data is used to improve services and how the data is integrated in both the clinic's and the hospital's quality assurance programs; and
- (6) Be signed and dated by the Hospital Administrator, Hospital Vice President of Nursing or Clinical Services, Hospital Hematopoietic Progenitor/Stem Cell Transplantation Program Director, Clinic Medical Director and Clinic Physician or Nurse Coordinator.